TOOLS FOR THE FIELD, TESTING AND TRACEABILITY IN THE DISTRIBUTION OF FOOD INGREDIENTS

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Trace ability throughout a food system has been a growing trend over the past few years. Quality assurance and quality testing within the food chain has been performed to some level throughout the latter part of the 20th century. With the Advent of HACCP (Hazardous analysis of critical control points) in the early 1990's, food safety has increased tremendously. With the introduction of Genetically Engineered food (GE) into the food chain, an entire new level of scrutiny has been leveled onto suppliers whom historically, performed very little testing or tracking of their products- the commodity and primary raw ingredient manufacturer.

Introduction

Analytical testing and diagnostic equipment as it relates to food and ingredient testing is estimated at 300 million dollar business annually in the United States, when GE or GMO testing is added to the number it increases by an estimated 39 million dollars per year. Food and product safety is extremely important and has been in the forefront of public awareness and concern for quite some time. Testing and tracking is performed within our food productions systems for several reasons, the main being human health and safety concerns, the second largest being brand and company protection. This paper will address some of the trends in testing that have been observed in the testing market over the past few years. It will also look at the trend in testing and trace ability further back into food production, to the production of commodities and primary ingredients. This paper will also discuss how testing needs to be real time, accurate and reliable as well as cost effective.

Testing, What and Why?

Typically testing, i.e. bacteriological tests or content ingredient testing is performed as a product approaches the consumer market. Certificates of analysis or "COA's" are commonplace and required in a food manufacturing facility. Testing is to ensure that the final food product that we as a consumer purchase and subsequently ingest is indeed safe, and labeled correctly. The USDA has published numerous guidelines, and testing and inspecting protocols for the safe handling and inspection of food products. The FDA watches labeling and health claims for foods very closely for truth and accuracy. The companies who "assemble" our finished food products, those that are sold on the shelf in grocery stores and markets are very regulated with regard to food safety. These companies need to know that the product they bake, mix, cut-up, process and package will meet the standards put forth by the government as well meet the expectations of the consumers they serve. Typically testing will occur with the inbound raw ingredients in order to insure integrity, protein content, moisture, and quality. Testing will then be performed as a product is assembled and prepared for packaging. This type of testing would be for bacteriological contamination, nutrient content, molds and fungi as well as foreign material. Assays would be performed in compliance with the labeling requirements, for such things as electrolyte content, proteins and fat analysis and the like. One must understand that different food products require different testing protocols that are intrinsic to the nature and type of food product. This regimen of testing has become very commonplace in the food ingredient and final food production arenas. Systems have been put in place that review personnel, equipment, procedures and ingredients. Again HCCAP and ISO protocols have greatly increased the ability for food to be traced to where, how and when it was handled. Difficulty has arisen when these types of testing and tracking procedures have been expected of the commodity handlers and producers who bring the raw ingredients to the food companies.

Genetically Engineered Crops As an Impetus for Further Testing

Genetically Engineered or GE crops as they will subsequently be referred to in this paper, have not, to date fallen into the realm of a food safety issue. There has been no substantiated data to remotely suggest that consuming GE foods is detrimental to the health and well being of our populace. The great "Taco Debacle" of 200 brought to the forefront a need for awareness and subsequent testing for an "unapproved for human consumption" type of corn. This yellow corn was a type of GE corn that had a genetic event inserted into it's DNA called Cry9C, the commercial name was Starlink® and was

distributed by the bio-tech seed company Aventis. This corn was a Bt variety, which allowed the corn to be insect resistant. Starlink had not been approved for human consumption due to questions surrounding the amount and size of the protein that was expressed by this particular variety and whether it might be an allergen in the human diet. It was decided by the FDA that this corn could be produced solely for animal feed. As we all know, in September of 2000, Starlink corn was found in taco shells made from yellow corn. This finding prompted the recall of over 300 products, the turning back of several barges and ocean going vessels full of corn bound for export and cost producers and food companies millions of dollars. This incident brought to the forefront many of the issues surrounding GE crops and also opened the door for comprehensive testing.

Testing for GE Commodities

With the Starlink® incident bringing GE crops into the public crosshairs, it became evident that a rapid, reliable and low cost method of detection for this and other proteins was needed. The Starlink® event really mandated a type of testing and true trace ability that had never really been required of the grain industry. Testing had been working its way slowly into a soybean market in 1999, but that testing was basically utilized for export markets that demanded a non-GMO product for the EU and Japanese markets. Very little of the domestic market was impacted by testing for Round-up Ready® Soybeans. Starlink® differed in the impact, it became a domestic issue, and given the vast amount of corn produced and consumed domestically it suddenly became a huge problem. Fortunately there were methods for the detection of the Starlink® protein. In the field farmers, grain elevators, millers and bakers were supplied with fast and reliable immunoassay lateral flow strip tests. Unfortunately a zero tolerance was imposed a threshold limit. In theory to achieve absolute zero, every kernel of corn would have had to be tested. Since this was not likely, statistical theory was used to establish sample size and number in order to achieve (in the field under production conditions) a 0.017% content. The USDA validated this method and the technology as an appropriate test method for the detection of the Cry9C protein. Other methods of detection are PCR (Polymerase Chain Reaction) and ELISA micro titer plates. The former is a very appropriate for raw ingredients and products that have not been highly processed the latter two methods work very well as a second method confirmation when time is not supercritical or for more highly processed foods. The Starlink® incident really acted as a catalyst for not just testing but trace ability as a whole. This really brought the concept of Identity Preservation into the daily lexicon of many grain elevators and producers.

Identity Preservation

Identity Preservation has been defined as a program or system that provides a comprehensive record for a product from the seed to the finished product. It is a program that will provide the commodity or food ingredient buyers proper chain of custody documentation and validation for their labeling programs. Identity preservation and trace ability has been practiced for years in the seed production industry. It is highly critical that the particular hybrid, or genetically modified seed that is being sold to a producer is at least 98% pure, so the concept of Identity preservation or IP is well entrenched and practiced in these facilities. IP began to move into the producer, elevator, and ingredient manufacturer as a way to 1. Know what is contracted is indeed delivered and 2. To provide a higher quality and possibly safer product to the consumer market. IP can take on many formats and protocols, however the basic premise is trace ability and the level of trace ability is usually determined by risk analysis. An IP system can be extremely detailed and tracked with a variety of electronics, testing protocols, third party auditing, and internet-based as well as hand-carried document trails. The critical quality points must be evaluated for risk and an appropriate method of minimizing that risk will be employed. IP systems are very personalized for individual companies, products and processes. Cost is another important issue that firms participating, they must evaluate if the cost of the IP system is commensurate with the level of confidence they need to achieve. This level of confidence may be required in a particular contract from the ultimate purchaser of product or from regulation, as we have seen from proposed trace ability guidelines from Europe. Some companies prefer a vertically integrated approach to “knowing what they grow”. These companies will contract directly with farmers as well as seed companies in order to ensure the integrity of the type and quality of products grown. My observation has been that even with a vertically integrated system, testing is still performed in both the field and at transfer points, especially when brand protection is a concern. Testing methods and technologies serve to support IP, and are not unto themselves indicative of a complete IP system. When used correctly, they are excellent tools to support a total quality system and themselves can act as indicator to potential safety issues early on in a process.

Field Testing Methods and Applications

Field methods for testing have been available for many years. Historically the opinion of field-based technologies has been that they are not as accurate or reliable as a classical laboratory based method. Field methods have made huge advancements in the past decade with the advent of miniaturization, solid-state circuitry, lateral flow immunochemistry and simplified wet chemistry methods. These field-based methods are in many cases just as, if not more accurate than first generation methods, and they accelerate a testing process, thus allowing real time reliable results in the field. As I stated before, not all Identity

Preservation programs require a tremendous amount of testing. An IP system can be a paper trail with third party validation of a process or be quite heavy with different testing and inspections. Currently an examination of and testing of grain is performed when the grain is brought to elevators or commercial storage. These test are for moisture, physical characteristics, foreign material, filth, GE's percentage and mycotoxin content. The standards for these tests are set forth by USDA/GIPSA in order to grade grain, but also to use appropriate and validated technologies to test it. The current methods for GE testing in the field are predominately immunoassay based. This is an antibody antigen reaction placed in a lateral flow format. This format ensures testing is fast (< 5minutes), simple and inexpensive (<$3.00). More intensive, quantitative methods can then be employed to confirm positives, or as the commodity is processed further into a secondary or tertiary raw ingredient. Often times as the commodity moves through its processes appropriate testing is layered into the process. This testing can be for protein content, amylase, bacterial content as well as bioavailabity testing. All of this testing and scrutiny through out a system leads to the end result of a high quality safe product for consumers.

GE Testing, Identity Preservation and its Potential Impact on Safety and Quality

An observation that others in my field and I have seen with regard to the impact that increased scrutiny and IP has had on grain, is that the quality of product has increased in some markets. Industries that have been requiring IP programs due to GE issues have found that their raw ingredients have in many cases been better than they had seen previously. This logical shift may be contributed to the fact that many commodity products that are IP'd are not blended, or mixed with other components. There is less chance (in theory) for a product to become adulterated in a well-planned and executed IP and testing program. It stands to reason that when consumers require a pedigree of this type, then potential liability is shared with everyone who had anything to do with the production of a consumer good. IP also has a place with regard to homeland security and our heightened need to protect ourselves from deliberate outside attack on our food production system. We could identify, if not prevent an adulteration with appropriate IP protocols in place. Identity preservation and testing removes some if not all in some cases, the anonymity associated with the grain industry. This is not to say that millions of tons of commodity goods do not move from farm, to elevator, to processor or rail car, to river terminals, export terminals and ends at a dinner table in London without it's origins ever being known. This happens every day and will continue to occur. Identity Preservation is not necessary for every crop or every application. Genetic Engineering and Modifications are here in our society to stay and with the advent of more output traits that would have direct consumer benefit IP and testing will be paramount in the use and marketing of these crops. Labeling is also another driver towards comprehensive IP and testing programs.

Conclusions

In the United States, we have many regulations and agencies whose main directives are keeping our foods and ingredients safe and nutritious. We as citizens have come to expect high quality, nutritious and safe products on our dinner tables. The vast majority of food companies in the United States strive everyday to produce and protect a safe consumer product. This awareness of safety, this commitment to excellence is what motivates companies towards testing methods, towards Identity Preservation and field based real time methods, towards accountability and towards continuing to produce high quality safe products for not only the people in our local communities, but the people of our global community.